

A Randomized Controlled Trial on The Effects of the Chinese Medical Nutrition Therapy (CMNT) Diet on Type 2 Diabetes: Study Protocol

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Study protocol

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Abstract

Background : Type 2 diabetes (T2D) has become a serious clinical problem since it has affected more than 463 million people. The importance of individual nutrients, foods, and dietary patterns in the prevention and management of type 2 diabetes is highlighted. Chinese Medical Nutrition Therapy (CMNT) is a special dietary intervention pattern featuring traditional Chinese medicine (TCM). The aim of the study is to determine the effect of the CMNT diet on remission of T2D.

Methods : This study is a randomized, controlled, parallel-group study. Seventy-two T2D patients will be randomly allocated to receive the CMNT diet (n = 36) or to continue their usual diet (as a control, n =36) at a 1:1 ratio for 90 days. Anthropological measures and biochemical assessments, including glycosylated haemoglobin (HbA1c) and plasma lipid profiles, will be performed in from patients at baseline and at the end of the study. The primary outcome is the diabetes remission. Secondary outcomes are HbA1c, fasting blood glucose (FBG), 2-h postprandial blood glucose (PBG), plasma lipid profiles, blood pressure, body mass index, treatment satisfaction and quality of life.

Discussion: Preclinical data showed that the CMNT diet decreased the blood glucose level, improved insulin resistance and promoted β -cell regeneration. However, clinical evidence is lacking. The present study will help in understanding the potential effect of the CMNT diet on the remission of T2D patients. Consumption of the CMNT diet might decrease the blood glucose level and improve glucose and lipid metabolism. If the CMNT diet demonstrates a significant clinical effect for T2D, it will inform clinical guidelines for the management of T2D in the future.

Trial registration : The trial was registered on [chictr.org.cn](http://www.chictr.org.cn/showproj.aspx?proj=60970). (Chinese Clinical Trial Registry, ChiCTR) Identifier: ChiCTR2000038036. Registered 9th of September, 2020; retrospectively registered, <http://www.chictr.org.cn/showproj.aspx?proj=60970>.

Background

Type 2 diabetes (T2D) is a chronic metabolic disorder characterized by persistent hyperglycaemia[1]. An abnormal increase in blood glucose may be due to insufficient insulin secretion and/or insulin resistance, resulting in metabolic disorders of carbohydrate, fat and protein[2]. In 2019, the 9th edition of the International Diabetes Federation (IDF) Diabetes Atlas showed that approximately 463 million adults aged 20 to 79 years develop diabetes globally (1 in 11 will be diabetic) and that 4.2 million people die from diabetes or its complications[3]. Diabetes is a potent risk factor for cardiovascular disease (CVD), blindness, renal failure, and lower limb amputation [4–6].

Medical nutrition therapy (MNT) is essential for the optimal management of T2D in adults [7]. It is an evidence-based application of nutrition care process interventions, including nutrition therapy, energy restriction and carbohydrate counting [8]. The evidence from randomized controlled trials, observational studies, and meta-analyses reveals that nutrition intervention improves metabolic outcomes, such as blood glucose and HbA1c levels, in individuals with diabetes. In randomized controlled trials in 2,595

patients who received intensive nutrition therapy, HbA1c decreased by 1.9% (from 8.9 to 7%) during 3 months of intervention[9]. A systematic review and meta-analysis suggested that healthy plant-based foods, such as fruits, vegetables, whole grains, legumes, and nuts, are associated with a lower risk of T2D[10]. Fasting blood glucose levels can be normalized by instituting a substantial negative calorie balance by dietary intervention. This rapid change relates to a substantial decrease in liver fat content and the return of normal hepatic insulin sensitivity [11].

Intermittent fasting is increasing in popularity as a means of losing weight and controlling chronic diseases [12]. It is an effective way to increase insulin sensitivity[13], reduce weight and fat mass[14] and improve blood lipid levels[15]. A randomized controlled trial compared participants who followed 3 months of an unrestricted diet to participants and who consumed fasting-mimicking diets (FMDs) for 5 consecutive days per month for 3 months. Three FMD cycles reduced body weight, trunk, and total body fat, lowered the fasting glucose and blood pressure and decreased insulin-like growth factor 1 (IGF-1)[16]. A randomized noninferiority trial shows that intermittent energy restriction is an effective alternative diet strategy for the reduction of HbA1c levels that is comparable to continuous energy restriction in patients with T2D[17].

Diabetes is well known as 'Xiao Ke' in traditional Chinese medicine (TCM)[18]. Treatment with TCM has been shown to yield stable efficacy, lower toxicity and few adverse reactions[19] for at least 2000 years. Some TCM themselves are foods, which is a concept referred to as 'medicine and food homology (MFH)'. The concept was mentioned in Huang Di Nei Jing as follows: 'eating on an empty stomach as food and administering to the patient as medication'[20]. In addition to nutritional value, MFH materials also have bioactive compounds that are useful in the prevention and treatment of disease [21].

CMNT is proposed on the basis of MNT and is an intervention for improving the health status or treat diseases by adding TCM nutrition and trace elements with medicine food homology (MFH) to change the nutritional status [22]. CMNT emphasizes a low glucose index (GI), low calories and low carbohydrates, high unsaturated fatty acids, high intestinal nutrition and high homology of medicine and food [23–24]. Preclinical data from our team, which compared the db/db mice fed a usual diet (n = 20) to the CMNT diet (n = 20) for 91 days, showed that the CMNT diet significantly reduced fasting glucose, improved insulin resistance and increased fasting insulin levels. Immunofluorescence double staining (insulin + PCNA) showed that the CMNT diet promoted cell proliferation, reversed db/db mice cell defects, and increased α -cells and β -cells to restore islet structure. The CMNT diet might remit diabetes and improve the quality of life in clinical practice.

We present the protocol of a randomized, controlled clinical study investigating the effects of the CMNT diet compared to a usual diet. We evaluated the diabetes remission, which was defined as HbA1c within normal range ($\leq 7.0\%$) and without antidiabetic medications for six months. In addition, we observed the HbA1c, fasting blood glucose, and 2-hour postprandial blood glucose levels of the participants before and after the intervention. We hypothesize that the CMNT diet will be superior to the usual diet after intervention compared to baseline, achieving the purpose of remission of T2D.

Methods And Design

Study design

The study is a randomized, controlled intervention trial examining the effects of the CMNT diet in T2D patients. It will be conducted at the Jinheyuan Outpatient Department and the Department of Shizi Mountain primary care in the local community. The trial is designed according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 checklist. After recruitment, participants' general information on diet, physical activity, and type and dosage of medications will be obtained. After written informed consent, the participants will be screened further for eligibility. Individuals likely to be ineligible or unsuitable to approach because of comorbidity or other practical or medical obstacles to participation will be removed from the investigation. Each participant will receive a unique identifier upon study entry. This identifier will be used for all data documentation to ensure the participant's confidentiality.

Randomization sequence of participants will be done by a statistician not involved in the trial using SAS software, version 9.4 (SAS Institute). Then, participants will be randomized at a ratio of 1:1 to the CMNT group or control group. Participants in the intervention group will receive the CMNT diet, whereas the other participants will receive the usual diet for 90 days. To evaluate participants' compliance, five 24-h dietary recalls will be taken throughout the intervention. All measurements, including anthropometric and biochemical assessments, will be examined at baseline and at the end of the trial. The coordinating centre holds trained physician for conducting study visits and taking informed consent, a study nurse for coordinating study visits and obtaining data during study visits. Any modification to the current study protocol will be submitted to the institutional review board, all trial participants and the trial investigators.

Recruitment

Patient recruitment strategies include specific study calls on the diabetes website and the holding of lectures for patients in specialized diabetes practices. When potentially eligible subjects are interested in participation, physicians will fully explain and discuss the study. The diagram (Figure 1) shows the participant flow through the trial.

Participants

Seventy T2D patients will be randomly allocated to receive the CMNT diet or to continue their usual diet as a control for 90 days.

Inclusion criteria

Participants who meet all the following criteria can be included in this trial:

- Patients with a diagnosis of T2D
- Patients with age > 18 years and < 75 years

- Patients with T2D who meet the diagnostic criteria for diabetes issued by the World Health Organization in 1999
- Patients taking T2D medications
- Patients with a body mass index between 18 and 35 kg/m²
- Patients who are willing and able to accurately use a home glucose metre for the self-monitoring of blood glucose
- T2D patients who have an urgent desire to fully understand the CMNT theory to improve their physical conditions
- Patients who can understand and follow the trial procedures and voluntarily participate in the trial
- Patients who provide informed consent

Exclusion criteria

Patients who meet any of the following criteria will not be allowed to participate in this trial:

- Type 1 diabetes or secondary diabetes due to pancreatic injury (such as Cushing's syndrome or acromegaly)
- Having used other drugs that may affect blood glucose metabolism in the last two months, including systemic glucocorticoids (except inhaled or topical), growth hormones, etc.
- Having used antihypertensive drugs or blood lipid regulating drugs used, but with the dose before screening not reaching a stable state

A history or condition of any of the following heart problems within the last 6 months:

- Decompensated cardiac insufficiency (NYHA grade III or IV)
- Unstable angina pectoris, myocardial infarction, coronary artery bypass grafting or stent implantation history
- Uncontrolled or severe arrhythmias (such as long QT syndrome, etc.) that have been evaluated by the investigator as inappropriate to participate in this clinical trial
- Haemorrhagic stroke or ischaemic stroke in the last 6 months rendering the individual ineligible to participate in this clinical trial as assessed by the investigator
- Presence of cerebral thrombosis, cerebral vascular blockage, cerebral haemangioma, mini-stroke, cerebral haemorrhage, cerebral stroke, cerebral infarction, cerebral infarction, hydrocephalus, brain tumour (malignant) and other diseases
- History of carotid artery stent implantation
- Urinary system with nephrotic syndrome, uraemia, polycystic kidney, kidney transplantation, lateral kidney removal/congenital single kidney, renal atrophy, renal tumour
- Digestive system with liver ascites, liver cirrhosis, liver flukes, severe hepatitis, varicose gastric fundus

- Nervous system with cerebellar atrophy, demyelination, cerebral palsy, Parkinson's disease, mania, schizophrenia
- Pulmonary embolism and pulmonary heart disease in the respiratory system
- Circulatory system with arterial rupture
- Immune system with Bezier's disease or eruption of lupus erythaematosus
- Presence of chondrosarcoma, liposarcoma, brucellosis, leukaemia
- History of malignancy within the last 5 years or current assessment for potential malignancy
- Proliferative retinopathy or macular disease accompanied by instability or requiring treatment in the last 6 months
- A history of diabetic ketoacidosis and hyperosmolar nonketotic coma in the last 6 months
- Present history of arteriosclerosis obliterans of the lower limbs
- Severe infection or trauma within the last month
- History of ≥ 2 episodes of severe hypoglycaemia in recent years
- Presence of a clinically significant urinary/reproductive infection, history of complex urinary tract infection, or history of recurrent urinary tract infections in the last 6 months.
- Uncontrolled hypertension with systolic blood pressure ≥ 160 mmHg and/or diastolic blood pressure at screening/baseline of 100 mmHg or higher; systolic blood pressure ≤ 90 mmHg and/or diastolic blood pressure ≤ 60 mmHg
- Current presentation of thyroid dysfunction that is not steadily controlled
- A history of other serious endocrine diseases, such as multiple endocrine neoplasms
- A history of diabetic ketoacidosis and hyperosmolar nonketotic coma in the last 6 months
- A history of severe liver and kidney disease
- Suspected or confirmed history of alcohol or drug abuse
- Blood donation or blood loss ≥ 400 mL within the last 3 months
- Serious mental illness or language impairment; unwillingness or inability to fully understand and cooperate with the study
- Pregnancy and breastfeeding
- Known alcohol and drug abuse
- Other conditions that the investigator considers inappropriate for participation in this study

Written consent is obtained from participants after a full explanation, an information leaflet is offered, and time is allowed for consideration. The participants have the right to refuse or continue to participate in this study without giving reasons. The chief investigator ensures that participant confidentiality is respected and local data protection requirements are met.

The retention of patients is promoted by close and frequent contact with their nutritional counsellor and physician *via* telephone, email and study visits. In case of relevant issues, visits outside the study

schedule are offered. Discontinuation study criteria include withdrawal of consent, subsequent occurrence of an exclusion criterion (e.g., change toward uncontrolled hypertension), lack of compliance and medical reasons for stopping the intervention.

Food records measure compliance with the intervention. For the CMNT group, there are regular additional meetings during each of the periods. These meetings have to be attended, enabling physicians and nutritional counsellors to evaluate compliance.

Interventions

Dietary intervention

During the 90-day experiment, participants will be randomized to the CMNT group or control group. The CMNT group will receive the CMNT diet for 5 consecutive days followed by 10 days of the usual diet, while the control group will receive only the usual diet for 15 days. The use of antidiabetic medications will be continued during the study. Multivitamin and mineral supplementation will be administered throughout the intervention. TCM nutritional intervention food contains a variety of oats, mulberry leaves, *Poria cocos*, *Siraitia grosvenorii* and other MFH natural raw materials or extracts (The ingredients of the CMNT diet are listed in Table 2). Both groups follow-up for 180 days.

The physician will educate each participant on the fundamentals of each dietary intervention and provide food lists. The physician will also be easily assessable to each participant for guidance and/or advice throughout the study. Ultimately, these measures should assist with participant compliance. Participants physical activity of CMNT group and control group follow the treatment guidelines for type 2 diabetes. The questionnaire also asks for information on the duration, type, and intensity of any exercise.

Medications

The process and rate of any medication reduction will be judged clinically and will depend on glycaemic control. There are clear specific recommendations for each of these medications and other classes of agents. During the intervention, the adjustment of anti-diabetic agents follows the following principles:

1. When participants achieved FBG (fasting blood glucose) or PBG (postprandial blood glucose) ≤ 5 mmol/L, the physician will reduce the usage of antidiabetic medications.
2. If FBG ≤ 5 mmol/L, priority should be given to reduce medium, long-acting and ultra long-acting hypoglycemic agents; If PBG ≤ 5 mmol/L, it will reduce the short-acting and ultra short-acting hypoglycemic agents of corresponding meals.
3. If the action duration of the agents is same or similar, the agents reduced according to the priority: insulin>insulin secretagogues agent>non-insulin secretagogues agent.
4. The recommendation of specific dosage reduction is provided by physician.

Adverse events

There are no major risks for patients participating in this study. We do not expect serious adverse events due to our dietary interventions. The materials or extracts in the CMNT diet are all foods in China, thus, the safety risk is under control. Patients will be asked regarding the tolerability of the interventions, and any adverse events will be recorded. Physicians will be asked to inform the research team about serious adverse events (SAEs) and adverse events (AEs). Participants will be asked at every visit about SAEs and AEs, which will be recorded at study visits and during telephone contacts with the research team.

Safety assessments

The trial is conducted in compliance with Good Clinical Practice principles (with which all investigators are confirmed to be familiar) and the applicable regulatory requirements. The study is subject to inspection and audit by the [National Health and Family Planning Commission](#), Adherence to Good Clinical Practice in Research.

Outcomes

The endpoint will be assessed by an experienced evaluator who is blinded to both clinical data and allocation. All outcomes will be measured at baseline and at the end of the dietary intervention.

Primary outcomes

To evaluate the remission effect of the CMNT diet, our primary outcome is the diabetes remission which is defined as a glycated haemoglobin (HbA1c) level of less than 7% (<53 mmol/mol) after at least 6 months off all antidiabetic medications.

Secondary outcomes

Anthropological measures, biochemical assessments and questionnaires will be evaluated.

- Glycosylated haemoglobin (HbA1c)
- Fasting blood glucose (FBG), postprandial blood glucose (PBG)
- BMI
- Systolic and diastolic blood pressure
- Total cholesterol, triglycerides, HDL cholesterol, LDL cholesterol
- Measure of quality of life from EQ-5D-5 L

Assessments

Home assessments

During each dietary intervention, in addition to daily dietary recall, fasting blood glucose and postprandial blood glucose will be assessed.

Laboratory assessments

Anthropometry, that is, height (to the nearest centimetre) and body mass (to the nearest 100 g), will be measured using a stadiometer and electronic scale, respectively. Participants will be measured without shoes and while wearing light clothing[25]. The questionnaires employed in the project have been validated or used previously in similar settings. The EQ-5D-5 L is a validated quality of life questionnaire that measures the effects of disease and health status on perceived quality of life. It describes 5 health-related quality of life dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression), all of which can take one of 3 or 5 responses depending on the level of severity[26-27].

Blood sampling and collection

After an overnight fast (minimum of 10 h), a 10-ml venous blood sample will be drawn by venous puncture from the brachial vein of the participant for the assessment of biomarkers of metabolic health. These biomarkers include HbA1c, triglycerides, LDL, HDL and total cholesterol.

Blinding

The CMNT is a diet intervention, so it is difficult to achieve double blindness. The control group only continues to maintain their usual diet and exercise habits. In the dietary intervention study, it is not possible for participants or all study personnel to be blinded to the group assignment. The study will be assessor-blinded, as the nurses who will perform the data collection (e.g., anthropometrics, doses of medications and blood pressure) and the technicians conducting laboratory work will be blinded to the intervention assignment.

Data collection and management

Data management

The Electronic Data Capture (EDC) system will be used for data management, including data entry, query, coding, security, and storage. Data will be gathered in source documents and then transferred onto paper case report forms. The data will be locally collected and transferred to the EDC system. The data will be coded and anonymised and then stored in an encrypted folder in a password protected computer. To improve the accuracy of data entry, entries will be verified for the proper format and expected range, as well as double-checked. Overall data quality will be assured by independent monitoring throughout the study.

Analysis Statistical methods

Data analysis will be performed using IBM SPSS Statistics (version 23, IBM Corporation, NY, USA). Two-tailed statistical significance will be accepted at $P < 0.05$. Continuous variables will be compared between the two groups by the independent sample t test, whereas the chi-square test will be used to compare categorical variables. Normally distributed continuous variables will be reported as the mean \pm SD. For binary outcomes, presentation of both absolute and relative effect sizes. The estimated effect size will be reported its precision such as 95% confidence interval. Multiple imputation will be used for missing data. We will adjust our final results for potential confounding factors using multivariable regression modelling.

Sample size

The primary outcome is the diabetes remission. Assuming a one-sided type I error of 5% and a power of 80%. According to primary care-led weight management for remission of type 2 diabetes (DiRECT)[11], calculations assumed diabetes remission in 22% of participants in the intervention group (the effect size deemed potentially important, a priori) compared with an estimated 5% in the control group. Accounting for an approximate 15% dropout, a total of 72 participants were recruited. the sample size was calculated using the following formula:

$$n = \frac{\pi_1(100 - \pi_1) + \pi_2(100 - \pi_2)}{(\pi_2 - \pi_1)^2} \times f(\alpha, \beta)$$

An interim analysis for futility and efficacy is planned at the midpoint of the trial. At this point the sample size may also be re-assessed.

Publication policy

The study results will be disseminated by peer reviewed scientific journals, internal reports, conference presentations and publication on websites. No identifiable personal data will be published. All anthropometric and personal clinical data will be expressed as the mean/median and spread of the population in the study. All participants will be informed of the results at the conclusion of the study, and details of any publications that arise from the study will be disseminated to participants. We will comply with the official eligibility guidelines for authorship for all publications and do not intend to use professional writers.

Monitoring

Throughout the study, an independent monitoring manager monitors study documents. Four nutritional scientists/dietitians are responsible for the implementation of nutritional interventions and have frequent personal contact with study physicians. Study team and principle investigators meet every month to supervise, review and discuss study progress and all study related issues. A safety report will be submitted to the Medical Research Ethics Committee every year.

Discussion

To the best of our knowledge, no previous studies have investigated the effect of the CMNT diet in T2D. To date, this is the first study that investigates the CMNT diet remission of T2D patients. Many TCM formulations have been used as food for long-term consumption and are safe and effective. TCM has the characteristics of multiple targets, multiple links and multiple pathways in treatment[28], which can not only reduce blood glucose but also control diabetic complications and has great advantages in diabetes rehabilitation. TCM contains many active compounds that might target multiple proteins in the biological network and effectively relieve T2D [29]. Natural hypoglycaemic ingredients studied clearly in TCM at present are divided into polysaccharides, saponins, alkaloids, flavonoids, and terpenoids by chemical structures[30]. MFH is a category of TCM, and there are food classes that can also be used as medication. In the CMNT diet, high MFH is employed for rehabilitation of T2D patients.

The meal pattern of CMNT in the diet is intermittent fasting. The advantage of intermittent fasting is that people have a major dietary adjustment for a few days every month and can thereafter return to a more normal diet. Intermittent fasting is an alternative dietary strategy for weight management and improving metabolic health. Dietary intervention studies cannot be blinded completely. Thus, expectations and observer bias cannot be ruled out. However, we will try to minimize bias by not communicating any longitudinal data during the study to patients and the study personnel who are in contact with them. Even more important, as the study research nurses who will perform the data collection (e.g., anthropometrics, drug doses and blood pressure) and the technicians measuring laboratory work will be blinded to the intervention assignment. Evaluation of the primary outcome is blinded for both clinical data and interventional allocation. Controlling and ensuring adherence to dietary interventions is rather challenging. This can only be avoided by close and frequent contact between nutrition counsellors and patients. Patients with suspected or known lack of compliance are excluded from the analysis.

There is little understanding of how the CMNT diet affects various physiological measures of T2D. The study aims to improve diabetes significantly or potentially put it into remission. Thus, our primary outcome is the withdrawal rate of antidiabetic medications after intervention compared to baseline. The CMNT diet potentially enhances the physical sustained remission to a nondiabetic state, improves quality of life and reduces the medical burden. In conclusion, the CMNT diet has the potential for remission of T2D. The study might close the gap between promising preclinical data and the lack of clinical data.

Trial status

Ongoing protocol version: 2.0. The recruitment began on 2 December 2019 and was completed on 10 November 2020. The date of the last visit is expected on 15 August 2021.

Abbreviations

Chinese Medical Nutrition Therapy (CMNT), Type 2 diabetes (T2D), traditional Chinese medicine (TCM), and medicine food homology (MFH)

Declarations

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Authors' contributions

DL is the Chief Investigator for the study. XY contributed to designing the study, developing the protocol, supervising the study progress and drafting the manuscript or revising it with critical input. RW managed and coordinated the performance of all aspects of the study. XK and WL contributed to the data analysis plan and prepared the data for analysis. XL and LY contributed to the data preparation and statistical analysis. All authors read and approved the final version of the manuscript.

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Availability of data and material

Data sharing is not applicable to this article, as no datasets were generated or analysed during the current study.

Ethics approval and consent to participate

The study has been approved by the Ethics Committee of the China Clinical Trial Registry (ChiECRCT20200235). All participants will sign a written informed consent form. Study protocol amendments are reviewed for approval by ethics committees when necessary. Written consent is obtained from each participant after a full explanation, an information leaflet is offered and time is allowed for consideration. The right of the participant to refuse to participate or continue participating without giving reasons and without prejudicing further treatment is respected. The Chief Investigator ensures that participant confidentiality is respected and local data protection requirements are met.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Tables

Due to technical limitations, table 1 is only available as a download in the Supplemental Files section.

Table 2. Macronutrient composition and components of 5-days CMNT diet.

Nutrition Information	Value
Energy (kJ/day)	3490.3
Energy (kcal/day)	835
Carbohydrate (%)	46
Protein (%)	8
Fat (%)	46
Saturated (g)	26.9
Monounsaturated (g)	42.3
Polyunsaturated (g)	28.7
Trans Fat (g)	0.3
Cholesterol (mg)	15
Fiber (g)	62.5

1. Compound Nutrient Rice: rice power, millet power, *Ganoderma lucidum*, corn, Ginseng, buckwheat, quinoa, oats, spinach powder, lily root flour, Cucumber powder, *Lentinus edodes* powder, mulberry leaves, *Poria cocos*, *Siraitia grosvenorii*, wheat dietary fiber, bitter gourd, pumpkin, purple sweet potato, sweet potato, potato, mung bean, yam, puerarin, soybean protein, wolfberry, *Cordyceps militaris*, konjac powder.

2. Solid Beverage: pumpkin seed oil, tea polyphenol, isomaltose oligosaccharide, casein, resistant dextrin, sodium ascorbate, potassium citrate, single and double high fatty acid esters, vitamin E, silica.

3. Nutritional Biscuits: wheat flour, whole milk powder, vegetable fat powder, white kidney bean powder, quinoa powder, maltodextrin, whey protein powder, curry powder.

4. Vegetable Porridge: pumpkin, pumpkin seed oil, maltodextrin, isomaltose oligosaccharide, casein, resistant dextrin, sodium ascorbate, potassium citrate, single and double glyceryl fatty acids, vitamin E, tea polyphenols.

Table 3. Baseline characteristics

	CMNT Group	Control Group
Sex		
Female	7 (21.9%)	11 (35.5%)
Male	25 (78.1%)	20 (64.5%)
Age (years)	52.7±6.20	55.1±11.7
BMI (kg/m ²)	24.6±1.80	23.7±2.1
HbA1c		
%	7.65±1.41	7.50±1.38
mmol/mol	59.92 (15.06)	58.47±15.10
Fasting plasma glucose(mmol/l)	8.15±2.31	7.83±2.14
blood pressure		
Systolic blood pressure (mm Hg)	129.41±6.94	128.66 ±6.87
Diastolic blood pressure (mm Hg)	84.41±4.33	84.00±3.56
Number of Glucose-lowering medications		
1 glucose-lowering agent	1.84(0.68)	1.94(0.60)
2 glucose-lowering agent	13(40.6%)	10 (32.3%)
3 glucose-lowering agent	11 (34.4%)	13 (41.9%)
EQ-5D scale score	8 (25.0%)	8 (25.8%)
EQ-5D scale score	76.31±5.38	77.32±5.49

Data are n (%), mean (SD) unless otherwise indicated. EQ-5D=EuroQol 5 Dimension

Figures

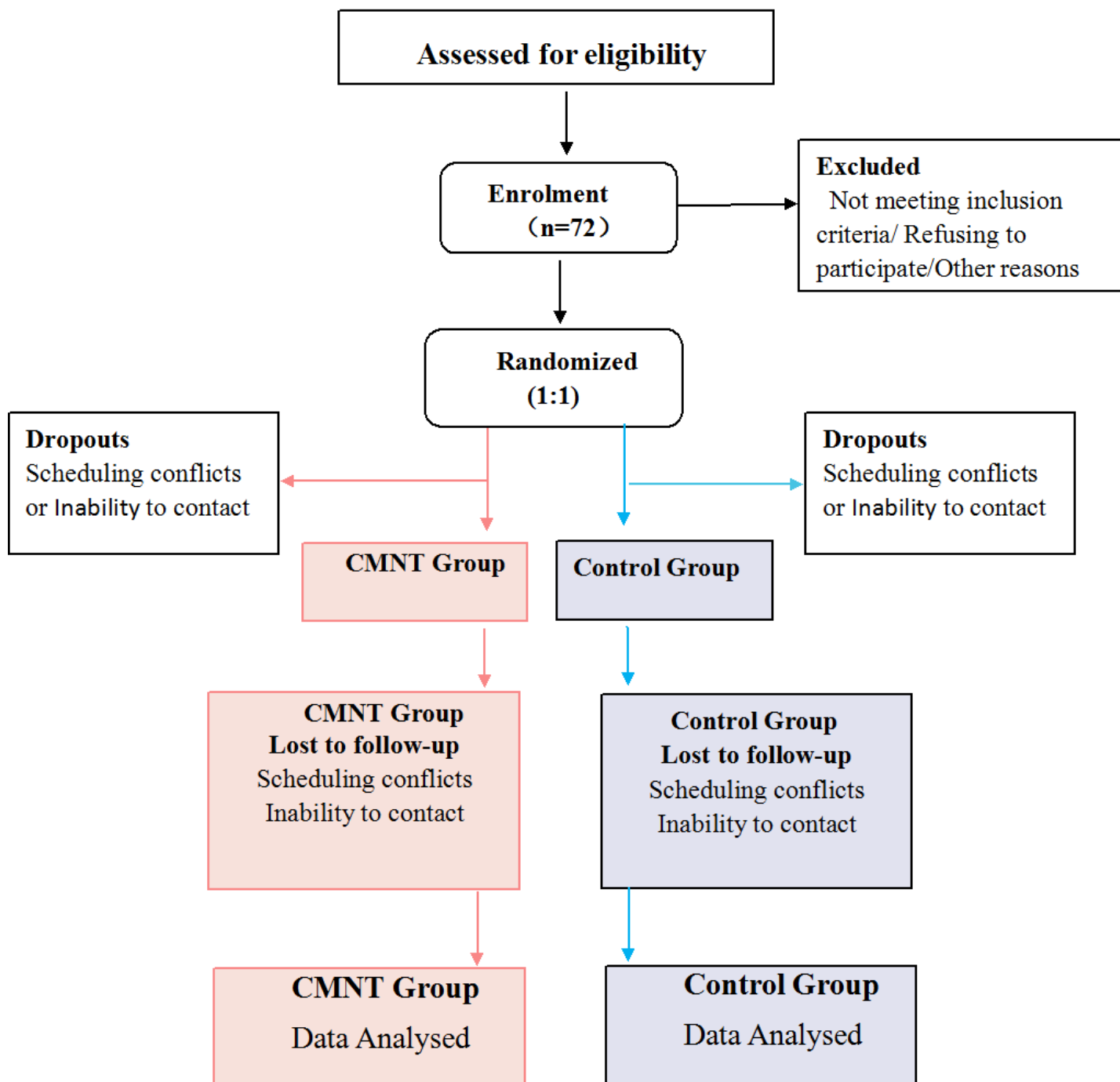


Figure 1

Diagram Showing Participants Flow through the Trial

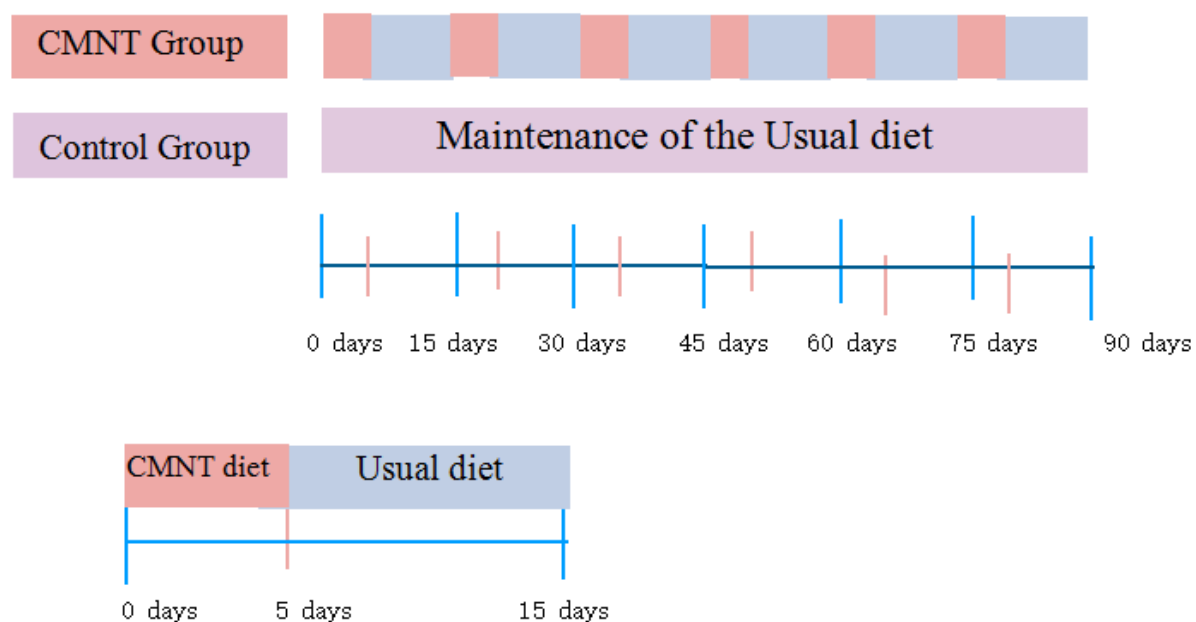


Figure 2

Scheme of the CMNT Interventions

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [CONSORTChecklistChineseHerbalMedicineFormulas.doc](#)
- [Table1.jpg](#)